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BD

Indispensable to human health

November 10, 2000

Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville. MD 20852

RE: **Docket No. 00N-1494** "Agency Information Collection Activities; Proposed Collection: Comment Request; Medical Devices; Classification/Reclassification; Restricted Device: Analyte Specific Reagents"

BD Biosciences appreciates the opportunity to comment on the Analyte Specific Reagent (ASR) regulation, originally promulgated November 23, 1998. While the ASR regulation has achieved an important public health goal in providing an opportunity for manufacturers to provide important reagents for home brew assays, our customers have encountered a number of difficulties working within the limitations of the existing regulation. Some of these deal specifically with the restrictions for the instructions for use, warnings and precautions, and product support.

Below please find our specific recommendations.

1. Instructions for Use

Current: The ASR regulation currently states that an ASR must be labeled in accordance with 21 CFR 809.10(e). This section does not allow for instructions for use for ASRs. In the Federal Register Notice, 21 Nov. 1997, page 62252; the supplemental information to the ASR regulation, the FDA indicated that the products were restricted to high complexity laboratories because ASRs in these labs would be handled by individuals whose training and experience are likely to assure the safe and effective use of these reagents. It has been our

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experience that not all lab personnel working in a high complexity laboratory have such knowledge of basic assay development.

Proposed: Medical device manufacturers shall provide basic laboratory instructions for use and warn against uses that are not appropriate for the particular ASR. This would not include instructions for data interpretation nor would it include claims for precision or accuracy.

Discussion: Manufacturers have basic information about specific reagent characteristics to assist labs in setting up their testing procedures and to alert labs of important pitfalls to avoid. This information is often obtained from customer complaints and subsequent investigations into the root cause of these problems, which could be of service to other customers. Under the current labeling regulations, we as manufacturers are not permitted to provide basic information with respect to proper use of the reagent in an assay.

Providing additional reagent specific information would help customers develop better assays and avoid making critical errors when generating laboratory data.

Most clinical labs are under tight financial restrictions; therefore, education of the laboratory technician may be one of the first items to get cut from the laboratory's budget. For this reason, providing information limited to reagent characteristics under different laboratory conditions would lend critical support to laboratory technicians and help assure that the best data possible is generated for interpretation by the healthcare professional.

Without any instructions for use or guidance on warnings and precautions, a greater incidence of more critical product problems may result in an increased risk to public health.

2. Warnings and Precautions

Current: "A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product"[1] is allowed in the current regulations.

Proposed: A guidance or written clarification as to the scope of appropriate warnings and precautions would be helpful.

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[1] 21 CFR 809.10(e)(1)(v)

Discussion: It is often very difficult to provide adequate warnings and precautions in the absence of being able to offer specific instructions for use. We would like to assist FDA in developing a guidance as to the permissible scope of the warnings and precautions section and to acknowledge that this section may be in conflict with the restrictions of other labeling sections. Without any instructions for use, laboratorians are at liberty to use products in very diverse ways. In order to maintain the expected reagent characteristics, limited acceptable instructions for proper handling of the reagents are needed.

3. Product Support

We have a responsibility to ensure that our products work properly in the hands of our customers. We have found that many customers requiring technical support are performing analyses at an unsatisfactory level. We have considerable knowledge about our reagents that would greatly benefit our customers. We want to make sure that our customers know how to properly set up our instruments, prepare samples, and generate good quality data. BD Biosciences believes it is in the best interests of patient care to be able to respond fully to customer technical inquiries. Data interpretation and medical diagnosis, in conjunction with other clinical information, would remain a medical responsibility outside of this regulation.

We appreciate the opportunity to comment on the current ASR regulation. We also appreciate FDA's ongoing efforts to create a better, less burdensome regulatory environment that retains as its central theme the protection of public health.

Sincerely,

JoAnn F. Gonzales for

Nancy E. Isaac, J.D., M.P.H.
Vice President, Regulatory Affairs
BD Biosciences

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